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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,690	01/09/2001	Orville G. Kolterman	030639.0066.UTL	4666

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/756,690	KOLTERMAN ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *16-18, 21-23 and 38-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,19,20,24-37 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's amendment filed on 10 September 2003 is acknowledged and entered. Following the amendment, claims 1, 5-7, 10, 24, and 28-30 are amended.

Currently, claims 1-41 are pending, and claims 1-15, 19, 20, 24-37 and 41 are under consideration.

Withdrawal of Objections and Rejections:

The rejection of claims 5-7, 14, 28-30 and 36 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment and argument.

The enablement rejection of claims 1-15, 24-37 and 41 under 35 U.S.C. 112, first paragraph is withdrawn in view of applicant's amendment.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 6, 9-14, 19, 20, 24, 26, 28, 29, 32-36 and 41 remain rejected under 35 U.S.C. 102(b) as being anticipated by Beeley et al. (WO 98/30231), and as evidenced by Beers et al. (the Merck Manual, 17th edition, pages 200-203), for the reasons of record set forth in the last Office Action, paper No. 25, at pages 5-6.

Applicants argument filed on 10 September 2003 has been fully considered, but is not deemed persuasive for reasons below.

At page 9 of the response, the applicant argues that the claimed methods as amended include identifying a patient with elevated triglyceride levels, that although Beeley does discuss the use of exendins in the lowering of plasma lipids generally, the reference does not discuss the use of exendines in the reduction of triglycerides specifically, which are a subset of total plasma lipids, nor does it teach or suggest the identification of a subject with elevated triglyceride levels,

and that the reference does not recognize the ability of exendins to specifically lower trilycerides as an independent mode of action. This argument is not persuasive for the following reasons. Although Beeley does not specify lowering triglyceride levels using exendins, as addressed in the last Office Action, it is well known in the art that the major plasma lipids are cholesterol and triglycerides (see attached the Merck Manual reference, page 200, the last paragraph of the left column). Additionally, it is well known that cholesterol and triglycerides are measured by separate methods (see attached the Merck Manual reference, the paragraph bridging pages 202 and 203). As such, a person of ordinary skill in the art would understand that "lowering plasma lipids" would require measuring *both* cholesterol and triglyceride levels in order to determine whether the plasma lipid levels of a subject are elevated prior to administering exendins. Therefore, the step of measuring or identifying triglyceride levels is inherently indicated by the reference, and the reference anticipates the present claims. With respect to the mode of action, it is irrelevant so long as the method and its steps are anticipated by the reference.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 4, 7, 8, 25, 27, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beeley et al., WO 98/30231, as applied to claims 1, 3, 5, 6, 9-14, 19, 20,

24, 26, 28, 29, 32-36 and 41 above, for the reasons of record set forth in the last Office Action, paper No. 25, at pages 6-7.

Applicants argument filed on 10 September 2003 has been fully considered, but is not deemed persuasive for reasons below.

At page 10 of the response, the applicant presents the same argument as that for the 102(b) rejection above. This argument is not persuasive for the same reasons above.

Claims 15 and 37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Beeley et al., WO 98/30231, as applied to claims 1, 3, 5, 6, 9-14, 19, 20, 41 above, and further in view of Wagle et al., US 6,326,396 B1, for the reasons of record set forth in the last Office Action, paper No. 25, at pages 7-8.

Applicants argument filed on 10 September 2003 has been fully considered, but is not deemed persuasive for reasons below.

At page 10 of the response, the applicant argues that Wagle too does not recognize the ability of exendins to lower plasma triglycerides as an independent mode of action, and therefore, does not remedy the deficiencies of Beeley in this regard. This argument is not persuasive because, as addressed above, the necessity of identifying and treating a subject with elevated triglyceride levels is indicated in the Beeley reference. The Wagle reference is not used to complement the Beeley reference in this regard. Further, even if the mode or mechanism of action of exendins were new, it is irrelevant to the patentability of the method because a newly discovered mechanism/result of a known process or a known method directed to a same purpose is inherent, and does not render the claimed method novel.

Conclusion:

No claim is allowed.

Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
11/14/03

LORRAINE SPECTOR
PRIMARY EXAMINER